

REMARKS/ARGUMENT

The present invention relates to an improvement in an HRT method in which a selective estrogen receptor modulator (SERM) is administered. That method is improved by additionally administering an agent which exhibits progestogenic activity to the host in an amount effective to modulate the side effects of the SERM. It is respectfully submitted that the combination of Young and Rodriguez does not render claims 1, 2, 10, 12 and 13 obvious under 35 U.S.C. § 103. Withdrawal of the rejection and allowance of the application is respectfully requested.

At the best, Young teaches the use of a SERM in HRT. As such, Young simply teaches the method which is being improved in the present invention.

Rodriguez teaches clomiphene was associated with increased risk of ovarian cancer in some women (column 2, lines 20-24) in the background section of the patent. Rodriguez itself is concerned with preventing the development of ovarian cancer by administering progestin products either alone or in combination with other agents. It is noted that column 4, lines 45-47 state that the progestin product is administered according to a regimen that is different from that used for HRT. Accordingly, reliance on Rodriguez in connection with an HRT method invention is clearly contraindicated.

The Office Action asserts that it would be obvious to use a progestin in connection with the HRT use of Young in order to achieve the beneficial effect of preventing the development of ovarian cancer. It is respectfully submitted that this is nothing more than a hindsight justification for the proposed combination and that is insufficient. A retrospective justification for the combination claimed in the present application does not render the invention obvious. There is clearly no motivation suggested in either of the references for the proposed combination. Rodriguez teaches non-use of an HRT regimen.

In light of the foregoing considerations, it is respectfully submitted that this application is now in condition to be allowed and the early issuance of a notice of allowance is respectfully solicited.

Respectfully submitted,



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